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10/750,271	01/02/2004	Andrew J. Dosmann	MSE #2652	1709

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EXAMINER	
TURK, NEIL N	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,271	DOSMANN ET AL.	
	Examiner	Art Unit	
	NEIL TURK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 21-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Remarks

This Office Action fully acknowledges Applicant's remarks made on May 2nd, 2008. Claims 1-10 and 21-32 are pending. Any objection/rejection not repeated herein has been withdrawn by The Office.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter within **claim 10**. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 10 requires that exactly four over illumination redirection facets, in which at least two are each disposed at approximately a 45 degree angle from the illumination light guide. Applicant's specification, however, as shown in paragraph [0018] of the pre-grant publication 2004/0142370 discloses four facets 22, 24, 26, and 28 that reflect input light approximately perpendicular to the illumination light guide 18. This description, however, does not disclose the respective 45 degree angle of at least two facets with respect to the illumination light guide. Thereby, Applicant must provide proper antecedent basis in the specification for such limitations. Applicant's pre-grant publication in paragraph [0020], for example, describes a single redirection facet 30 disposed at a 45 degree angle relative to the illumination light guide 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, **7-9, 21-24, and 29-32** are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (4,803,992), hereafter Lemelson.

Lemelson discloses a catheter or device 10 with an elongated housing 11 that includes a cable 21 (illumination input area at the offset of the cable) formed of four separate light pipes 22 (an illumination light guide), 24, 26, and 28 (detection guide, passing light to a photoelectric detector at the output of light pipe 28; lines 25-41, col. 4). Lemelson further discloses that a cavity 16 (read window disposed approximately perpendicular to the input light path) is formed in the front end portion 13 that allows light energy to be directed therethrough to scan fluent material, such as body fluid existing in the cavity (line 38, col. 3 – line 2, col. 4; fig. 1). Lemelson also discloses that the device contains a plurality of reflecting surfaces 14 and 15 (two overillumination redirection facets to redirect light away from the illumination light guide) for respectively receiving light energy passed through the lens 23 of light pipe 22 from a source light and is then directed to reflect off reflecting surface 15 to receiving lens of the light pipe 28 along which it passes to a photoelectric detector coupled to the other end of light pipe 28 (lines 3-54, col. 4). With regard to claim 2, Examiner asserts that reflecting surface 14 is between the illumination light guide and the read window. With regard to claim 3, reflecting surface 15 is between the read window and the detection guide. Examiner asserts that Lemelson reads on claim 24 as discussed directly above with respect to reflecting surfaces 14 and 15.

Claims 1-3, 7, 9, 21-24, and 29-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Meserol (EP 0254246 A2).

Meserol discloses an improved cuvette. Meserol discloses a cuvette 10 in combination with a lancet 12 (extending outwardly from read window 22), where the cuvette has a top 14 and a bottom 15, closed wall 18, access slot 20 and a cavity 22 (for fluid, such as blood) (lines 25-40, col. 4, figs 1-4). Meserol discloses that the cavity 22 may be filled with a medium such as an optically transparent gel provided with a reagent test system (lines 8-21, col. 5). Meserol also discloses integrally formed optical elements, such as light beam 30 from source 32, which passes through the cuvette (input area and illumination light guide is defined in the optically transmissive portion of the cuvette where light enters from source 32) and is reflected by reflecting prism 50 across cavity 22 (read window disposed approximately perpendicular to the input light path) to reflecting prism 48 (reflectors 48 and 50 constitute the one or more overillumination redirection facets) and back out through the sample cuvette (detection guide is defined in the optically transmissive portion of the cuvette where light is reflected back and out of the cuvette) to optical element 36 (detection element at the outlet end of the detection guide) (lines 1-42, col. 5; lines 10-41, col. 6, figs 5&6). With regard to claim 2, reflecting prism 50 is between the illumination light guide and the read window. With regard to claim 3, reflecting prism 48 is between the read window and the detection guide. Examiner asserts that Meserol reads on claim 24 as discussed directly above with respect to prisms 50 and 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lundsgaard et al. (5,525,518), hereafter Lundsgaard.

Meserol has been discussed above.

Meserol discloses a lancet for obtaining a sample, but does not disclose that the lancet is adapted to deposits the sample onto the read window.

Lundsgaard discloses a needle 20 and sampling cavity connected for determination of a blood gas parameter in which the needle draws a blood sample through aperture 21 and into the conduit 21 down through measuring chambers 300, 400, 500, 600 (lines 52-67, col. 7, fig. 3).

It would have been obvious to modify the Meserol device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample onto the read window in order to allow for direct sample deposition on to the test area, so as to avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Naka et al. (6,001,307), hereafter Naka.

Meserol has been discussed above.

Meserol does not disclose reagent provided on the read window.

Naka discloses an optical analyzing device in which when the covering 5a is transparent and light may be irradiated through the covering, a reagent film impregnated with a reagent may be stuck on the inner surface of the covering 5a (lines 38-46, col. 10, fig. 1a-b).

It would have been obvious to modify the Meserol device to include reagent provided on the window such as taught by Naka, such that it would be obvious to place

the reagent on the window (or any location), in which location the reagent will come into contact with the sample as desired for an assay with sample and reagent interacting.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson.

Lemelson has been discussed above.

Lemelson does not disclose that the detection guide cross-sectional area is larger than the illumination light guide cross-sectional area.

It would have been obvious through routine experimentation to optimize the Lemelson device to the relative cross-sectional dimensions as recited in the claim in order to provide an optimal light path through the device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol.

Meserol has been discussed above.

Meserol does not disclose that the detection guide cross-sectional area is larger than the illumination light guide cross-sectional area.

It would have been obvious through routine experimentation to optimize the Meserol device to the relative cross-sectional dimensions as recited in the claim in order to provide an optimal light path through the device.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Lipson et al. (4,710,623), hereafter Lipson.

Lemelson has been discussed above.

Lemelson does not disclose at least three overillumination redirection facets.

Lipson discloses an optical fiber catheter with a reactive element contained therein. Lipson discloses an optical cable 12 with a hole 18 for holding a reactive element 20. Lipson discloses that a reflective coating 22 may be applied to outer surfaces of the cable, and the reflective coating may be constructed to be wavelength specific, whereby certain wavelengths of light are reflected and others are allowed to be transmitted out of the first end 14. Lipson discloses that this significantly improves the ability of the system to quantify the desired information by reducing or eliminating wavelengths of light passing through but not interacting with the reactive element (column 4, figs. 1&2). Lipson further discloses that the amount of alteration or change in a property of the incident light 38 is dictated by the change in the property of the reactive element 20 as it interacts with the blood, or other bodily fluid. Lipson discloses that the change in the incident light 38 is a function of the reaction between the reactive element and the fluid to be analyzed(lines 53-67, columns 5; column 6). Examiner asserts that, as shown in figure 2, the reflective coating 22 covers four surfaces, which each constitute an overillumination redirection facet.

It would have been obvious to modify the Lemelson device to include four overillumination redirection facets such as taught by Lipson as another design means for analyzing bodily fluid characteristics through light interaction and alterations.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson.

Meserol has been discussed above.

Meserol does not disclose at least three overillumination redirection facets.

Lipson has been discussed above.

It would have been obvious to modify the Lemelson device to include four overillumination redirection facets such as taught by Lipson as another design means for analyzing bodily fluid characteristics through light interaction and alterations.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson as applied to claims 25 and 26 and in further view of Lundsgaard.

Meserol discloses a lancet for obtaining a sample, but Meserol in view of Lipson does not disclose that the lancet is adapted to deposits the sample onto the read window.

Lundsgaard have been discussed above.

It would have been obvious to modify the Meserol/Lipson device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample onto the read window in order to allow for direct sample deposition on to the test area, so as to avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson as applied to claims 25 and 26 and in further view of Naka.

Meserol/Lipson does not disclose reagent provided on the read window.

Naka has been discussed above.

It would have been obvious to modify the Meserol/Lipson device to include reagent provided on the window such as taught by Naka, such that it would be obvious

to place the reagent on the window (or any location), in which location the reagent will come into contact with the sample as desired for an assay with sample and reagent interacting.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record, namely Lemelson, Meserol, or Lipson, does not disclose or suggest an optical format with exactly four overillumination redirection facets and wherein at least two of the four overilluminaiton redirection facets are disposed at approximately a 45 degree angle from said illumination light guide.

Response to Arguments

Applicant's arguments filed May 2nd, 2008 have been fully considered but they are not persuasive.

With regards to the objection to the specification not providing proper antecedent basis for the claimed subject matter of claim 10, Applicant traverses the rejection. Examiner notes that claim 10 has been amended to recite that at least two of the four overillumination redirection facets are disposed at approximately a 45 degree angle to the illumination light guide. Applicant argues that Figure 2 of Applicant's drawings shows at least one end of one or more overillumination redirection facets disposed at an angle approximating 45 degree relative to the illumination light guide 18. Applicant presents a similar argument with respect to figure 5 of Applicant's drawings.

Examiner first asserts that such an argument is not commensurate in scope with the claim limitations of claim 10. Applicant's argument is drawn to "at least one end of one or more overillumination redirection facets" and does not relate to two or more overillumination redirection facets disposed approximately at a 45 degree angle to the illumination light guide. Further, Applicant's written specification does not provide any antecedent basis for the recitation of claim 10. Examiner asserts that the drawings do not provide such antecedent basis for such limitations as the drawings are not to be to scale, so as to properly show the relative relationship claimed in claim 10.

With regards to claims 1-3, 7-9, and 21-24 rejected under 35 USC 102(b) as being anticipated by Lemelson (4,803,992), Applicant argues that Lemelson fails to disclose, teach or suggest one or more overillumination redirection facets located proximate to and in optical communication with the illumination input area and the illumination light guide, said one or more [the at least three] overillumination redirection facets adapted to redirect light overilluminating the illumination light guide away from the illumination light guide. Examiner first notes that Applicant's argument is drawn to a recitation not found in claim 1, as amended; Applicant's argument references "the at least three overillumination redirection facets" but such an argument is not scope with currently amended claim 1. Examiner will interpret the argument to read on the recitation present in the Listing of Claims for claim 1, which correctly recites, "...said one or more…". Examiner asserts that Lemelson does disclose such overillumination redirection facets in items 14,15 as both are proximate to (as they are close and within the same device as the input area and guide) and in optical communication with the

illumination input area at the offset of the cable, as well as with the input light guide 22, and both redirect light overilluminating the illumination light guide away from the illumination light guide, as the light progression path that the facets 14, 15 provide for, bring the light from the input illumination guide and both redirect it away and to the detection guide and back out in the opposite direction through a different guide. Additionally, Examiner asserts that the recitation to the adaptation of the at least one overillumination redirection facet is drawn to a functionality of the redirection facet that is not presented with any further positively recited structural elements or relationships. As such, as Lemelson discloses all of the previously recited structural elements and relationships within claim 1, the overillumination redirection facets 14, 15 are said to read on the "adapted to" functionality of claim 1.

Further, claims 2, 3, 7-9, and 21-24 are maintained rejected as there is no such deficiency in Lemelson with respect to claim 1.

With regards to claims 1-3, 7, 9, and 21-24 rejected under 35 USC 102(b) as being anticipated by Meserol (EP 0254246 A2), Applicant traverses the rejection. Applicant argues that like Lemelson, Meserol fails to disclose, teach or suggest one or more overillumination redirection facets located proximate to and in optical communication with the illumination input area and the illumination light guide, said one or more [the at least three] overillumination redirection facets adapted to redirect light overilluminating the illumination light guide away from the illumination light guide. Applicant further argues that reflecting prisms 48, 50 fail to redirect overilluminating light away from an illumination light guide, as recited in claim 1. Examiner argues that

Meserol does disclose such overillumination redirection facets as required by claim 1. Examiner argues that reflecting prisms 48, 50 (one or more overillumination redirection facets), as seen in figure 5, for example, are located proximate (as they are close and within the same device as the input area and guide) to and in optical communication with the light input area where light enters the optically transmissive portion of the cuvette and light guide defined by the optically transmissive medium in which the light from source 32 propagates therein. Further, prisms 48 and 50 both redirect light away from such input light guide so as to redirect the light across and back out through a different light guide, i.e. away from the input light guide.

Further, claims 2, 3, 7, 9, and 21-24 are maintained rejected as there is no such deficiency in Meserol with respect to claim 1.

With regards to claim 4 rejected under 35 USC 103(a) as being obvious over Meserol in view of Lundsgaard (5,525,518), **as well as claim 5** under 35 USC 103(a) as being obvious over Meserol in view of Naka (6,001,307), **and claim 6** rejected under 35 USC 103(a) as being obvious over Meserol, **as well as claim 6** rejected under 35 USC 103(a) as being obvious over Lemelson, Applicant traverses the rejection. Applicant argues that as discussed above, all the elements of claim 1 are not found in Lemelson or Meserol, a prime facie case of anticipation cannot be made for the above combinations over claims 4-6. Examiner asserts that as no such deficiency exists in Lemelson or Meserol, claims 4-6 are maintained rejected as discussed above.

With regards to claims 25-28 rejected under 35 USC 103(a) over the various combinations of art including Lemelson or Meserol in view of Lundsgaard, Lipson, and

Naka, Applicant traverses the rejection. Applicant argues that Lipson does not overcome the shortcoming of Lemelson or Meserol, as neither Lemelson nor Meserol fail to teach or suggest overillumination redirection facets adapted to redirect light overilliuminating the illumination light guide away from the illumination light guide, and claim 25 requires at least three such facets. Applicant argues that the disclosure of Lipson to reflective coating 22 does not add anything new to the citations from Lemelson or Meserol. Examiner asserts that as discussed above, the reflective coating 22 of Lipson, as seen in figure 2, covers four distinct surfaces for redirection, in which each surface constitutes an overillumination redirection facet. Thereby, Examiner asserts that Lipson does add to the disclosure of Lemelson and Meserol, and the combination of art reads on claims 25-28 as discussed above.

With regards to new claims 29-32, Applicant argues that the claims are allowable for many of the reasons recited above for independent claims 1 and 25. Examiner argues that as discussed above, newly added claims 29-32 are not allowable based on the new grounds of rejection applied above, as the disclosure of Lemelson and Meserol read on such limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

/Jill Warden/
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